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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/824,286

04/02/2001

Linda C. Burkly

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06/24/2002

BIOMEN, INC.
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Cambridge, MA 02142

EXAMINER

O HARA, EILEEN B

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 06/24/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/824,286

Applicant(s)

BURKLY ET AL.

Examiner

Eileen B. O'Hara

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-58 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-58 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-28, in so far as they are drawn to soluble gc chain blocking agent that is a gc binding polypeptide that is an antibody, or antibody homolog, hybridomas producing such or nucleic acids encoding such, classified in class 530, subclass 388.22, for example.
 - II. Claims 1-5, 25 and 26, in so far as they are drawn to soluble gc-blocking polypeptide, classified in class 530, subclass 350, for example.
 - III. Claims 1-5, 25 and 26, in so far as they are drawn to soluble gc mimetic agent, classified in class 530, subclass 300, for example.
 - IV. Claims 29-33, in so far as they are drawn to a method of raising an antibody comprising administering an immunogen comprising at least a portion of a gc chain to a mammal, classified in class 514, subclass 2.
 - V. Claims 34-37 and 44-51, in so far as they are drawn to a method for inhibiting functioning of the gc chain in vitro comprising contacting a cell with the soluble gc chain blocking agent of group I, classified in class 424, subclass 139.1, for example.
 - VI. Claims 34, 36, 44 and 45, in so far as they are drawn to a method for inhibiting functioning of the gc chain in vitro comprising contacting a cell with the soluble gc-blocking polypeptide of group II, classified in class 424, subclass 184.1, for example.

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- VII. Claims 34, 36, 44 and 45, in so far as they are drawn to a method for inhibiting functioning of the gc chain in vitro comprising contacting a cell with the soluble gc mimetic agent of group III, classified in class 424, subclass 184.1, for example.
- VIII. Claims 38-43 and 52-56, in so far as they are drawn to a method of treating an immunological disease comprising administering a composition which includes a gc-blocking agent from group I, classified in class 514, subclass 2, for example.
- IX. Claims 38, 39, 52-54 and 56, in so far as they are drawn to a method of treating an immunological disease comprising administering a composition which includes a gc-blocking agent from group II, classified in class 514, subclass 2, for example.
- X. Claims 38, 39, 52-54 and 56, in so far as they are drawn to a method of treating an immunological disease comprising administering a composition which includes a gc-blocking agent from group III, classified in class 514, subclass 2, for example.
- XI. Claims 57 and 58, in so far as they are drawn to a method of identifying a compound that non-competitively inhibits functioning of a cytokine receptor wherein the cytokine receptor utilizes gc as its receptor component, classified in class 435, subclass 7.1, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-III are related to each other in that they all are gc-blocking agents, but they are different chemical compounds because Invention I is antibodies or antibody homologs, the compounds of Invention II may be derived from the gc chain, and the compounds of invention III may be peptides, semi-peptidic compounds or non-peptide compounds, and thus are patentably distinct from each other.

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Inventions IV and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the method of making the antibody to gc chain of invention I can be used to make antibody to another distinct protein.

Inventions I-III are each related to invention XI in that the method of identifying compounds that inhibit functioning of a gc containing receptor can identify the compounds of inventions I-III, but the compounds of inventions I-III can also be used in a method of treatment, which is a materially different method.

Invention I is related to each of inventions V and VIII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies can be used in the method of contacting cells to inhibit functioning of the gc chain of invention V or in the method of treatment of invention VIII, but the methods are patentably distinct because they have different methods steps and goals.

Invention II is related to each of inventions VI and IX as product and process of use. In the instant case the gc-blocking polypeptide can be used in the method of contacting cells in vitro to inhibit functioning of the gc chain of invention VI or in the method of treatment of invention IX, but the methods are patentably distinct because they have different methods steps and goals.

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Invention III is related to each of inventions VII and X as product and process of use. In the instant case the gc mimetic agent can be used in the method of contacting cells in vitro to inhibit functioning of the gc chain of invention VII or in the method of treatment of invention X, but the methods are patentably distinct because they have different methods steps and goals.

Inventions II and III are each unrelated to invention IV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the gc-blocking polypeptide of invention II and the gc mimetic of invention III are not produced by the method of immunizing an animal to produce antibodies.

Invention I is unrelated to inventions VI, VII, IX and X. In the instant case the antibody of invention I is not used in the methods of the inventions.

Invention II is unrelated to inventions V, VII, VIII and X. In the instant case the of gc-blocking polypeptide of invention II is not used in the methods of the inventions.

Invention III is unrelated to inventions V, VI, VIII and IX. In the instant case the gc mimetic agent of invention III is not used in the methods of the inventions.

Inventions V-XI are each unrelated to the other because they have different starting materials, different method steps and goals and are thus patenably distinct.

2. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their different classification and /or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

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Species Election

3. If inventions VIII, IX or X is elected, claims 38-43 are generic to a plurality of disclosed patentably distinct species comprising myasthenia gravis, IBD, rheumatoid arthritis, lupus, multiple sclerosis, insulin-dependent diabetes, sympathetic ophthalmia, uveitis, allergy, asthma, parasitic disease, graft versus host disease (GVHD) and psoriasis.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from each of this group of species of the invention that is elected for further examination on the merits, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that are elected consonant with this requirement, and a listing of all claims readable thereon, including an claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species MPEP § 809.02(a).

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4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined and election of the species even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers Before Final filed by RightFax should be directed to (703) 872-9306.

Official papers After Final filed by RightFax should be directed to (703) 872-9307.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.

Patent Examiner



**ELIZABETH KEMMERER
PRIMARY EXAMINER**